

National Cancer Institute
Institutional Review Board
AGENDA (* revised 6/30/2015)
July 13, 2015
1:00 – 5:00
10 CRC/3-1608

- 1. Review of Draft Minutes, June 22, 2015**
- 2. Announcements**
- 3. Old Business**
 - Guidance to NIH Investigators with Protocols Involving PDS Products
- 4. New Business**
- 5. Problem Report Forms**
- 6. Other Expedited Actions**
- 7. Continuing Reviews**
- 8. Response to Stips** 03C0277-X, "Cell Harvest and Preparation for Surgery Branch Adoptive Cell Therapy Protocols" - Steve Rosenberg, PI
- 9. Response to Stips** P152199, "A Phase 2, Open-label, Single-arm, Intra-subject Dose-escalation Study to Investigate the Biological Activity, Safety, Tolerability, and Pharmacokinetics of Ponesimod in Subjects with Symptomatic Moderate or Severe Chronic GVHD Inadequately Responding to First or Second Line Therapy" - Steven Pavletic, PI
- 10. Response to Stips** P142109, "A Phase 1/2 Proof-of-Concept Study of the Combination of ACP-196 and ACP-319 in Subjects with B-cell Malignancies" - Mark Roschewski, PI
- 11. Response to Stips** 15C0012-B, "A Phase II, Open-Label, Multicenter Trial to Investigate the Clinical Activity and Safety of MSB0010718C in Subjects with Merkel Cell Carcinoma" - Isaac Brownell, PI
- 12. Response to Stips** *11C0113-J, "A Pilot Study of Genetically Engineered NY-ESO-1 Specific (c259) T Cells in HLA-A2+ Patients with Synovial Sarcoma"—Crystal Mackall, PI
- 13. Response to Stips** *09C0082-Z, "Assessment of the Safety and Feasibility of Administering T cells Expressing an anti-CD19 Chimeric Antigen Receptor to Patients with B-cell Lymphoma"—Steve Rosenberg, PI
- 14. Amendment** 14C0140-D, "A Pilot Study of 18F-DCFBC PET/CT in Prostate Cancer" - Liza Lindenberg, PI
- 15. Amendment** 15C0039-B, "Biomarkers in Acute Graft-Versus-Host Disease (GVHD) and Extracorporeal Photopheresis added to Investigator Chosen Therapies of Steroid Refractory Acute GVHD" - David Halverson, PI

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AGENDA (*continued*)

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| 16. Amendment | 13C0063-I, "A Phase I, Open-label, Multiple-ascending Dose Trial to Investigate the Safety, Tolerability, Pharmacokinetics, Biological and Clinical Activity of Avelumab (MSB0010718C), a Monoclonal Anti-PD-L1 Antibody, in Subjects with Metastatic or Locally Advanced Solid Tumors and Expansion to Selected Indications" - James Gulley, PI |
| 17. Amendment | 14C0056-B, "Collection of Blood from Patients with Ovarian, Primary Peritoneal or Fallopian Tube Cancer" - Christina Annunziata, PI |
| 18. Initial Review | P141582, "Phase I Study of Veliparib (ABT-888), an Oral PARP Inhibitor, and VX-970, an ATR Inhibitor in Combination with Cisplatin in Patients with Refractory Solid Tumors" - Alice Chen, PI |
| 19. Initial Review | P142104, "A Randomized, Double-blind, Placebo-controlled Study of the Safety and Efficacy of Amatuximab in Combination with Pemetrexed and Cisplatin in Subjects with Unresectable Malignant Pleural Mesothelioma" - Raffit Hassan, PI |